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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,043	10/04/2000	Erling Sundrehagen	REF/Sundrehagen/127	4723

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EXAMINER

COOK, LISA V

ART UNIT

PAPER NUMBER

1641

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13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/679,043

Applicant(s)

SUNDREHAGEN ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) 2-8 and 13-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected. → 1, 3 and 9?
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 and 13-25 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 10. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election without traverse of Group II (claims 1, 9, 10, and 12) in Paper No. 12, filed 12/05/01 is acknowledged. Pursuant to applicants' request-amendment-B, claims 1-3 and 19 were amended, while claims 9-12, 26, and 27 have been cancelled without prejudice or disclaimer.

2. The restriction requirement is deemed proper and is therefore made FINAL.

3. Currently claims 1-8 and 13-25 are subject to restriction and election requirement.

Claims 2-8 and 13-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non elected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 12.

4. Claim 1 (Group II) is pending and under consideration.

### *Priority*

5. Receipt is acknowledged of papers (Application No. 9820473.8 filed 9/18/98 in GB) submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

6. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The instant application does not contain the required first sentence referencing GB Application no. 9820473 filed 9/18/98. Please add to the specification.

***Information Disclosure Statement***

7. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered.

8. The information disclosure statements filed 1/23/01-Paper #4 and 12/5/01-Paper #10, have been considered as to the merits prior to first action.

***Drawings***

9. The drawings submitted in the instant application have been stamped approved by the Draftsperson under 37 CFR 1.84 or 1.152.

***Specification***

10. The disclosure is objected to because of the following informalities: A. Page 1 is not numbered. B. On page 30, example 9 rabbit is misspelled "rabit". Appropriate correction is required. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

11. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

In the instant application, the Brief Description of the Drawings is on page 27 before the examples. The description should follow the brief summary of the invention. See MPEP 608.01(f).

12. The use of several trademarks is noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. (For example, luminol on page 23, see page 28 – Abbot, Amersham on page 30, etc).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and indefinite because it is not clear what the assay method will detect. Initially the claim is directed to the determination of transcobalamin II (TC) bound cobalamin. However the claim further recites the measurement of holo-TC or TC II bound cobalamin content. Is it applicant intend to measure both? If holo-TC II and TC, are the terms to be used interchangeably, how will the measurement of only holo-TC II bound cobalamin relate to the TC II measurement? Please clarify the claim language. One acronym should be utilized for consistency.

B. Claim 1 is vague and indefinite in utilizing the phrase “an analogue or fragment thereof of cobalamin”. Because the method measures bound cobalamin it is not clear how the analogue will guarantee cobalamin binding. The phrase an analogue or fragment thereof of cobalamin” is not defined in the disclosure therefore the metes and bounds cannot be determined. One of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Morelli et al. (Journal of Laboratory and Clinical Medicine, March 1977, Volume 89, Number 3, pages 645-652).

Morelli et al. teach an assay method (radioimmunoassay) for determining transcobalamin II (TC II) bound cobalamin or vitamin B<sub>12</sub> (TC II-B<sub>12</sub>). A cell free sample of body fluid (conducted in either pure or crude preparations). Specifically the cells were removed prior to clotting in the samples (see page 646, serum for testing of immunoassay). B<sub>12</sub> was bound to TC-II then subsequently contacted with a specific binding ligand for the complex (TC II-B<sub>12</sub>). Free and bound fractions were collected and utilized to determine the amount of (TC II-B<sub>12</sub>) present in the test sample. See Measurement of total TC II-B<sub>12</sub> independent of immunoassay (page 646) and Final procedure (pages 648-649).

15. For reasons aforementioned, no claims are allowed

***Remarks***

16. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Allen et al.(US Patent #4,332,785) disclose an immunoassay utilizing immunoreactive proteins like transcobalamin II or transcobalamin II receptor to measure reticulocytes.( Abstract)

B. Herbert (US Patent #4,680,273) discloses assay methods to measure B12 deficiency.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook

CM1-7B17

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2/23/02



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02/25/02